

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V.,	)	
JANSSEN, L.P., and	)	
SYNAPTECH, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. Action No. 05-381 (KAJ)
	)	
BARR LABORATORIES, INC.	)	
and BARR PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

**JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., AND SYNAPTECH, INC.'s  
REPLY TO COUNTERCLAIMS**

Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, “Janssen”), and Synaptech, Inc. (collectively, “Plaintiffs”), by their attorneys, reply to the Counterclaims of Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, “Barr”), as follows:

1. Paragraphs 1-37 of Barr’s Answer, Affirmative Defenses and Counterclaims to Complaint are not part of the Counterclaims and require no response by Plaintiffs.
2. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 38, and on that basis deny the allegation set forth therein.
3. In response to Paragraph 39, Plaintiffs admit that Janssen Pharmaceutica N.V. is a wholly-owned subsidiary of Johnson & Johnson, is a corporation organized and

existing under the laws of Belgium, and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

4. In response to Paragraph 40, Plaintiffs admit that Janssen, L.P. is a wholly-owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey, and has its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey 08560.

5. In response to Paragraph 41, Plaintiffs admit that Synaptech, Inc. is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

6. Plaintiffs admit the allegations of Paragraph 42, but deny that Barr has stated a claim upon which relief may be granted.

7. Plaintiffs admit the allegations of Paragraph 43.

8. Plaintiffs admit the allegations of Paragraph 44.

9. Paragraph 45 contains conclusions of law rather than allegations of fact for which a response is required. Insofar as a response is required, Plaintiffs deny the allegations of Paragraph 45.

10. Paragraph 46 contains conclusions of law rather than allegations of fact for which a response is required. Insofar as a response is required, Plaintiffs deny the allegations of Paragraph 46.

11. Paragraph 47 contains conclusions of law rather than allegations of fact for which a response is required. Insofar as a response is required, Plaintiffs deny the allegations of Paragraph 47.

12. Paragraph 48 contains conclusions of law rather than allegations of fact for which a response is required. Insofar as a response is required, Plaintiffs deny the allegations of Paragraph 48.

13. In response to Paragraph 49, Plaintiffs admit that the '318 patent is listed in the FDA "Orange Book" in connection with NDA No. 21-169.

14. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 50, and on that basis deny the allegation set forth therein.

15. In response to Paragraph 51, Plaintiffs admit that notice letters dated May 13, 2005 were received, which contain Barr's assertions concerning the '318 patent. Plaintiffs further admit that Barr's notice letter included a conditional offer to provide its ANDA to Plaintiffs. Plaintiffs further admit that they requested Barr's ANDA No. 77-605 by letter dated May 25, 2005, and that Barr provided such ANDA to Plaintiffs on June 6, 2005.

16. In response to Paragraph 52, Plaintiffs admit that on June 10, 2005, they filed a patent infringement lawsuit against Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. Plaintiffs further admit that their Complaint alleged that Barr's

ANDA products would infringe the '318 patent. Plaintiffs deny the remaining allegations of Paragraph 52.

17. In response to Paragraph 53, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

18. Plaintiffs admit the allegations of Paragraph 54, but deny that Barr has stated a claim upon which relief may be granted.

19. Plaintiffs admit the allegations of Paragraph 55.

20. In response to Paragraph 56, Plaintiffs state that Barr's Counterclaim speaks for itself. Insofar as a response is required, Plaintiffs deny that Barr has alleged any facts supporting its assertion that the '318 patent is not infringed or is unenforceable, but admit that Barr has denied that the patent is valid and enforceable.

21. Plaintiffs admit the allegations of Paragraph 57.

22. Plaintiffs deny the allegations of Paragraph 58.

23. In response to Paragraph 59, Plaintiffs deny that Barr has any additional defenses or counterclaims.

24. In response to Paragraph 60, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

25. Plaintiffs admit the allegations of Paragraph 61, but deny that Barr has stated a claim upon which relief may be granted.

26. Plaintiffs admit the allegations of Paragraph 62.

27. Plaintiffs admit the allegations of Paragraph 63.

28. Plaintiffs deny the allegations of Paragraph 64.

29. In response to Paragraph 65, Plaintiffs deny that Barr has any additional defenses or counterclaims.

30. Plaintiffs deny that Barr is entitled to any of the relief it has requested.

31. Any allegation not specifically admitted is denied.

32. Plaintiffs deny that Barr is entitled to a trial by jury based on any Count in the Complaint or any Counterclaim.

#### **Affirmative Defense**

33. Barr's Counterclaims are barred in whole or in part because they fail to state a cause of action upon which relief may be granted

#### **Prayer For Relief**

WHEREFORE, Plaintiffs seek the following relief:

- A. A judgment dismissing with prejudice Barr's Counterclaims and each and every Prayer for Relief contained therein;
- B. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- C. An award of costs and expenses of Plaintiffs in defending these Counterclaims;

- D. A judgment including each and every Prayer for Relief sought by Plaintiffs in the Complaint; and
- E. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

*/s/ John G. Day*

---

Steven J. Balick (Delaware Bar No. 2114)  
John G. Day (Delaware Bar No. 2403)  
222 Delaware Avenue  
17th Floor  
P.O. Box 1150  
Wilmington, DE 19899  
Tel: 302-654-1888  
Fax: 302-654-2067

Of Counsel:

*Attorneys for Plaintiffs*

George F. Pappas  
Roderick R. McKelvie  
Christopher N. Sipes  
Jeffrey B. Elikan  
Laura H. McNeill  
COVINGTON & BURLING  
1201 Pennsylvania Avenue, N.W.  
Washington, DC 20004  
Tel: 202-662-6000  
Fax: 202-662-6291

Steven P. Berman  
Office of General Counsel  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933  
Tel: 732-524-2805  
Fax: 732-524-5866

DATED: July 19, 2005

159663.1

**CERTIFICATE OF SERVICE**

I hereby certify that on the 19<sup>th</sup> day of July, 2005, the attached **JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., AND SYNAPTECH, INC.'s REPLY TO COUNTERCLAIMS** was served upon the below-named counsel of record at the address and in the manner indicated:

John C. Phillips, Jr., Esquire  
Phillips, Goldman & Spence, P.A.  
1200 North Broom Street  
Wilmington, DE 19806

HAND DELIVERY

George C. Lombardi, Esquire  
Winston & Strawn LLP  
35 West Wacker Drive  
Chicago, IL 60601

VIA FEDERAL EXPRESS

*/s/ John G. Day*

---

John G. Day